

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Guillermo J. Tearney et al.	
Application No.:	10/016,244	
Filing Date:	October 30, 2001	Examiner: Shawna Jeannine Shaw
Title:	JUL 11 2005 OPTICAL METHODS AND SYSTEMS FOR TISSUE ANALYSIS	Group Art Unit: 3737

DECLARATION UNDER 37 C.F.R. § 1.131

We, GUILLERMO J. TEARNEY and BRETT E. BOUMA, hereby declare as follows:

1. We are the joint inventors of the invention disclosed and claimed in U.S. Patent Application Serial No. 10/016,244 filed October 30, 2001 (the "244 App."), which claims priority under 35 U.S.C. § 119(e) from U.S. Patent Application Serial No. 60/244,255 filed October 30, 2000 (the "255 App.").
2. At the time the invention was made, we were employed by The General Hospital Corporation, the assignee of the entire right and interest to the above-identified application. We continue to be employed by The General Hospital Corporation.
3. We conceived the subject matter of the invention recited at least in independent claims 1 and 39 in the '244 App. (as amended in the attached Amendment) and described in the '255 App. on or before May 3, 2000. Further, the invention recited in pending claims 1 and 39 was reduced to practice at least as early as the filing date of the '255 application. We diligently worked on reducing the claimed invention to practice from the date of the conception thereof by providing the disclosure to a patent attorney, and working diligently with such patent attorney to file the '255 App.
4. In particular, on or before May 3, 2000, we conceived a method of analyzing tissue, in which a tissue is illuminated with coherent or partially coherent light, light reflected from the tissue is received at a detector, and a series of speckle patterns are formed, and changes in the speckle patterns are analyzed at time intervals sufficient to measure changes caused by microscopic motion of objects within the tissue, such that

the tissue is in vivo and/or the tissue is internal tissue (as recited in amended independent claims 1 and 39). This method was reduced to practice upon the filing of the '255 App.

5. In addition, on or before May 3, 2000, we conceived to practice a method of analyzing a tissue structure, in which a tissue is illuminated with coherent or partially coherent light, light reflected from the tissue is received at a detector, and a series of speckle patterns are formed such that the tissue is in vivo and/or the tissue is internal tissue, and speckle pattern data at time intervals sufficient to measure microscopic motion within the tissue structure or adjacent tissue, and the tissue structure is assessed by analyzing spatial characteristics of the speckle pattern data to deduce structural or biomechanical characteristics of the tissue structure (as recited in amended independent claim 39). This method was also reduced to practice upon the filing of the '255 App.

6. As evidence of the conception of the invention recited in amended independent claims 1 and 39 on or before May 3, 2000, attached hereto as Exhibit A is a copy of the eighteen (18) page presentation document entitled "Vulnerable Plaque Characterization Using Temporal and Spatial Speckle Analysis" (referred to herein below as "Presentation") which was prepared internally at least as early as May 3, 2000.

7. The attached document demonstrates that we conceived the method of the invention to analyze tissue and tissue structure at least as early as the completion date of the Presentation (i.e., on or before May 3, 2000). For example, the Presentation describes a receipt of a coherent interference of light remitted from a scattering media or substrate. (see, e.g., Presentation, p. 7). Further, the Presentation describes the formation of speckle patterns to be detected by indicating that, e.g.,

"Motion of a single scatterer in the specimen changes the speckle pattern

- The time dependent speckle pattern can be used to determine the Brownian motion within a multiply scattering media
- The motion is characterized by the spatial decorrelation of the speckle pattern as a function of time
- For Brownian motion, the decorrelation is a negative exponential with a time constant,  $\tau$ " (see *id.*)

8. In addition, the Presentation describes a determination of microscopic motion within the tissue and/or adjacent to the tissue, and also determining the spatial characteristics of speckle pattern data. For example, it is provided as follows:

"Spatial and Temporal Characterization of Plaques

Measuring the speckle decorrelation time,  $\tau$ , as a function of distance from beam entry point allows measurement of Brownian Motion and

- Cap thickness
- Cap stiffness
- Lipid pool stiffness" (see *id.*, p. 9).

9. The tissues being discussed in the Presentation are clearly provided in vivo and/or are internal tissues by referring to IVUS and OCT techniques which measure the tissues in vivo and/or internal tissues. Further, the Presentation describes the determination of the structural or biomechanical characteristics of the tissue structure. (See *id.*, pp. 3-5).

10. The invention as recited in now-pending independent claims 1 and 39 has been reduced to practice by filing the '255 App., which completely describes each of the features recited in these claims. For example, the '255 App. (a copy of which is attached herewith as Exhibit B), at least on pages 1-4 as well as in other portions thereof, clearly describes each and every feature recited in these claims.

11. We further declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements are made with the knowledge that the making of willfully false statements and the like is punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and may jeopardize the validity of any patent issuing thereon.

6/3/05

Date

  
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GUILLERMO J. TEARNEY

6/3/05

Date

  
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BRETT E. BOUMA